UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation This Document Relates to: All Actions	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY

TEVA'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* TO PRECLUDE DEFENDANTS FROM INTRODUCING EVIDENCE OF EVENTS OCCURRING ON OR AFTER MAY 27, 2014

Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively "Teva") respectfully submit this memorandum in opposition to Plaintiffs' Motion *In Limine* to Preclude Defendants from Introducing Events Occurring on or After May 27, 2014 (ECF No. 1071).

Plaintiffs' effort to preclude Teva from introducing such evidence is a transparent attempt to prevent the jury from hearing clear and dispositive evidence directly relevant to a central question in this case: would Teva have been able to launch a final FDA approved generic version of Nexium had Teva's patent litigation settlement with AstraZeneca not occurred and, if so, when? To this date no generic manufacturer has been able to procure tentative FDA approval for generic Nexium, let alone final approval, despite Teva's (and Ranbaxy's) May 2014 licensed entry date having come and gone. This fact directly undermines Plaintiffs' theory that Teva could have launched a generic Nexium prior to May 2014 absent settlement, and evidence relating to Teva's continued inability to obtain FDA approval, including official correspondence to and from the FDA, is admissible to demonstrate that Teva's FDA approval efforts continue without success. This evidence is also directly relevant to questions that Plaintiffs' own experts

have put at issue, including whether the FDA generally acts to grant approval at the time of a licensed entry date and when FDA approval might have occurred but for Teva's settlement with AstraZeneca. In this case, of course, the FDA has not approved any generic as of the May 2014 licensed entry date and Teva's FDA approval efforts have continued without resolution. Defendants should be permitted to introduce documentary evidence in the form of official FDA communications that contradicts the opinions of Plaintiffs' expert witnesses on these issues. The evidence sought to be excluded is highly and directly probative to causation — a material element of Plaintiffs' claims on which they bear the burden of proof at trial. Preclusion of this evidence would be improper and invite error for this reason alone.

Even beyond the substantial probative value of evidence demonstrating Teva's continued inability to obtain FDA approval, Plaintiffs' purported rationales for exclusion can also be soundly and quickly rejected on their own terms.

First, Plaintiffs' protestations that Teva has produced only post-May 2014 official communications between Teva and the FDA but has not engaged in a wholesale post-close-of-discovery search for Teva's *internal* communications, and that Plaintiffs were surprised by expert testimony on the status of Teva's FDA approval, ring hollow as a problem of their own making. As an initial matter, Plaintiffs themselves requested the production of all communications between Teva and the FDA concerning Teva's ANDA file since the close of discovery in this case. Teva acceded to that request and produced, on June 4, September 9, and October 6, additional ongoing FDA correspondence regarding Teva's ANDA. Moreover, Plaintiffs admit that *Plaintiffs themselves* refused to make a simultaneous supplemental production after the close of discovery despite Teva's contingent agreement that it would do so if Plaintiffs reciprocated, and further admit that Plaintiffs *did not move to compel* Teva to produce

any requested supplemental discovery. Having elected to forego reciprocal supplemental discovery and having failed to bring any motion to compel against Teva, Plaintiffs cannot now complain that they are unfairly prejudiced because they lack information they declined to pursue. Moreover, Plaintiffs' argument that Teva has attempted to "backdoor" such evidence into the case through its expert witness is absurd — Plaintiffs' own experts Blume and Morrison have put this evidence at issue by speculating, in supplemental reports served on September 15, 2014, that the FDA would have granted approval on Ranbaxy's and Teva's licensed entry date in the but-for world. Mr. Johnston's report merely responded to these arguments, in part by citing documentary evidence of FDA communications that directly contradict Plaintiffs' experts. There are simply no procedural grounds on which Plaintiffs may properly complain that they are "unfairly prejudiced" by Teva's introduction of highly relevant evidence of FDA communications in this case.

Second, Plaintiffs' "foundation" arguments merely go to the weight of the FDA approval evidence, and do not impact its admissibility. Recent correspondence to and from the FDA regarding the status of Teva's ANDA has a direct evidentiary foundation and relevance to primary issues in this case (just like the FDA's correspondence with Teva before May 2014). To the extent that Plaintiffs wish to argue that the evidence that the FDA still has not approved any generic Nexium product does not necessarily mean that FDA approval would not have occurred earlier in the absence of Teva's patent litigation settlement agreement with AstraZeneca, they are of course free do to so. But it does not follow that the FDA evidence is rendered inadmissible merely because it makes Plaintiffs' causation case harder to prove. To the contrary, because Teva's current inability to obtain even tentative FDA approval for its generic Nexium product is

highly probative of a central element of Plaintiffs' affirmative case, Teva must be permitted to disclose it to the jury.

Third, Plaintiffs' Rule 403 argument confuses unfavorable evidence undermining a central element in their case with the "***unfair*** prejudice" contemplated by the Rule. There is no doubt that the absence of tentative approval for any generic manufacturer is highly damaging to Plaintiffs' theory of liability and directly undermines a central element of their affirmative case to be proved — the allegation that Defendants' actions actually *caused* Plaintiffs' injury. But facts on the ground that directly contradict Plaintiffs' theory of the case are *fairly* and *properly* prejudicial to Plaintiffs' case — the very definition of admissible evidence that should be submitted to a jury. Moreover, as described above, the so called prejudice asserted by Plaintiffs amounts to nothing more than hand wringing over Plaintiffs' *own* decisions not to agree to reciprocal supplementation and not to pursue available remedies to compel any requested production. And in any event, even if there were *unfair* prejudice at issue here on that basis (and there is absolutely none), any such prejudice would be greatly outweighed by the substantial probative value of the evidence that Teva has not received FDA approval.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion *In Limine* to Preclude Defendants from Introducing Events Occurring on or After May 27, 2014 should be denied.

Dated: October 19, 2014

Respectfully submitted,

/s/ *Laurence A. Schoen*

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CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of October 2014, I filed and served the foregoing via the Court's CM/ECF system, which will serve notification of such filing by email to all counsel of record.

/s/ Laurence A. Schoen
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